PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
36437PC01		

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK2005/000133	25.02.2005	26.02.2004

International Patent Classification (IPC) or national classification and IPC
G01N33/497, C12Q1/24, G01N1/22

Applicant
THOMSEN BIOSCIENCE A/S

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
22.12.2005	06.02.2006

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/DK2005/000133

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-32	as originally filed

Claims, Numbers

1-13	received on 22.12.2005 with letter of 22.12.2005

Drawings, Sheets

1/8-8/8	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11,13
	No:	Claims	12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-13
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Reference is made to the following documents:

D1: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 2003, MAINELIS G ET AL: "Application of electrostatic precipitation for simultaneous determination of culturable and total airborne microorganisms." Database access. no. PREV200300546604;

D2: MAINELIS G ET AL: "Collection of airborne microorganisms by electrostatic precipitation" AEROSOL SCIENCE AND TECHNOLOGY, vol. 30, no. 2, 1999, pages 127-144;

D3: US 2003/136205 A1 (TOTOKI SHINICHIRO) 24 July 2003;

D4: WO 03/031067 A (MASSACHUSETTS INSTITUTE OF TECHNOLOGY) 17 April 2003;

D5: DE 2756164 A1 (BECK, CH) 21 June 1979;

D6: US 6126800 A (CAILLAT ET AL) 3 October 2000.

NOVELTY

The subject-matter of claims 1-11 and 13 is new in the sense of Article 33(2) PCT, as it is not comprised in the state of the art.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 12 is not new in the sense of Article 33(2) PCT. Document D3 (paragraphs [0117] - [0130] and figure 6) discloses a device containing

a chip site (electrode 4),

an electrical interface between the device and the chip for applying an electrostatic field between the electrodes,

a programmable unit comprising software for performing the application of an electrostatic field between the electrodes.

Consequently, the subject-matter of claim 12 is not new.

INVENTIVE STEP

The present application does not meet the requirements of Article 33(1) PCT, because the

subject-matter of claims 1-... does not involve an inventive step in the sense of Article 33(3) PCT.

Document D2 is the **closest prior art** (figure 2; page 133, right-hand column, paragraph 3; page 131, left-hand column, first paragraph). This document discloses methods for collecting and analysing biological particles from air comprising:

1) providing a sample chamber between two electrodes that are about 2.2 cm apart [this distance is inferable by the dimensions of the through, which is 4,8 cm wide],
2) providing a gaseous sample to the sample chamber,
3) applying a potential to the electrodes to electrostatically collect the biological particles,
4) contacting the biological particles collected in the sample chamber with a first liquid.
5) performing further analysis.

The **additional technical feature** of claim 1 over D2 is that the electrodes are at the most 2 cm apart.

The **problem** to be solved by the present invention may therefore be regarded as the provision of an alternative method for collecting and analysing biological particles from air.

The **solution** to this problem can be found in spacing the electrodes at the most 2 cm apart.

In order to provide an alternative setup it is merely a standard modification option to down size the electrode distance by 10%. Consequently, the subject-matter of claim 1 is obvious.

Dependent claims 2-9 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

Document D2 is the **closest prior art** (figure 2; page 128, last paragraph - page 129, first paragraph; page 129, last paragraph). This document discloses an electrostatic aerosol sampler used for the collection of biological particles where the collection surface was a glass plate (chip). Thus, D2 discloses a chip (glass plate):

1) comprised in a sample chamber comprising a gaseous sample said chamber

having two openings, one towards the air another towards a device, said sample chamber being between two electrodes that are about 2.2 cm apart

2) wherein inherently because of its use as a biological particle collector a biological particle is present on at least one of the two electrodes.

The **additional technical feature** of claim 10 over D2 is that the electrodes are at the most 2 cm apart.

The **problem** to be solved by the present invention may therefore be regarded as the provision of an alternative chip for collecting and analysing biological particles from air.

The **solution** to this problem can be found in spacing the electrodes at the most 2 cm apart.

In order to provide an alternative setup it is merely a standard modification option to down size the electrode distance by 10%. Consequently, the subject-matter of claim 10 is obvious.

Dependent claim 11 does not contain any features which, in combination with the features of claim 10 to which it refers, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT).

The subject-matter of claim 13 is not inventive in the sense of Article 33(3) PCT, because it merely concerns the juxtaposition of a known device and a non-inventive chip which are in the same technical field.

INDUSTRIAL APPLICABILITY

The subject-matter of claims 1-13 is industrially applicable in the field of biological particle detection.

36437PC01

PCT publication no.: WO 2005/083 391
Title: Method, chip, device, and system for collection of particles
Applicant: Thomsen Bioscience A/S
P&V reference: 36437PC01

Response to first Written Opinion dated 17 August 2005

AMENDED CLAIMS

1. A method for collecting, and optionally also detecting, a biological particle from air, the method comprising the steps of:

1) providing a sample chamber and a first and a second electrode, the first and the second electrode and the sample chamber being so positioned that at least a part of the sample chamber is between the first and the second electrode, and the first and a second electrode is separated by a distance being at the most 20 mm,

2) providing an gaseous sample in sample chamber,

3) applying an first potential to the first electrode and a second potential to the second electrode, thus resulting in a potential difference and an electric field between the first and second electrode, to assist electrostatic collection, in the sample chamber, of a biological particle in the gaseous sample,

4) contacting the biological particle collected in the sample chamber with a first liquid, and

5) subjecting the collected biological particle to further analysis.

2. The method according to claim 1, wherein the first potential of the first electrode and the second potential of the second electrode, and thus the electric field between the first and the second electrode, are selected so as to yield a capture efficiency of at least 50% for biological particles having an effective length in the interval from 1-10 micrometer.

3. The method according to claim 1 or 2, wherein the first and/or the second electrodes have a substantial form chosen from the group of: a sheet, a plate, a disc, a wire, a rod, a point; or any combination thereof.

4. The method according to any of the preceding claims, wherein the first and a second electrode are separated by a distance being at the most 10 mm.

5. The method according to claim 1, wherein at least a part of the gaseous sample in sample chamber is positioned or flows between the first and the second electrode.

6. The method according to any of the preceding claims, wherein the biological particle comprises a component selected from the group consisting of a microorganism, a virus, a plant spore, and a fragment thereof.

7. The method according to claim 6, wherein microorganism is a bacterial spore.

8. The method according to claim 7, wherein the bacterial spore is formed by a bacterium selected from the genus Bacillus and/or the genus Clostridium.

9. The method according to claim 8, wherein the bacterial spore is a spore formed by *Bacillus anthracis*.

10. A chip for collection of biological particles, the chip comprising a sample chamber comprising:

- a sample chamber with a first opening in fluid connection with the surrounding air and a second opening to form a fluid connection with a device, the sample chamber comprising an gaseous sample,
- a first and a second electrode positioned at opposing sides of the sample chamber, the first and a second electrode is separated by a distance of at the most 20 mm, and
- a biological particle attached to the first or the second electrode.

11. The chip according to claim 10, wherein the electric field magnitude is in the range of 50-2000 V/mm.

12. A device for collecting biological particles in a chip, the device comprising:

- a chip site where the chip is to be located in order be functionally associated with the device,
- an electrical interface between the device and the chip for applying an electrostatic field between the electrodes of the sample chamber, and
- a programmable unit comprising a software that effects that the device performs one or more actions selected from the group consisting of:

  - applying an electrical field between the first and second electrodes to assist electrostatic capturing, in the sample chamber, of biological particles in the gaseous sample,

  - contacting collected biological particles in the sample chamber with a first liquid reagent, and

  - performing further analysis of the collected biological particles by performing a nucleic acid amplification by operating a heating electrode.

13. A system for collecting biological particles, the system comprising a chip according to any of claim 10-11 functionally associated with a device according to claim 12.